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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/613,678

07/02/2003

Darrell C. Brett

ExpC:EptaRib

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07/12/2006

LAW OFFICE OF KAREN DANA OSTER, LLC

PMB 1020

15450 SW BOONES FERRY ROAD #9

LAKE OSWEGO, OR 97035

EXAMINER

SHAY, DAVID M

ART UNIT

PAPER NUMBER

3735

DATE MAILED: 07/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.		Applicant(s)	
	10/613,678		BRETT, DARRELL C.	
	Examiner		Art Unit	
	david shay		3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on April 14, 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on July 2, 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
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| <p>1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)</p> <p>2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)</p> <p>3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
 Paper No(s)/Mail Date <u>April 14, 2006</u>.</p> | <p>4) <input type="checkbox"/> Interview Summary (PTO-413)
 Paper No(s)/Mail Date. _____</p> <p>5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)</p> <p>6) <input type="checkbox"/> Other: _____</p> |
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A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on April 14, 2006 has been entered.

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the “internal energy application layer”; the “internal insulation layer”; “internal layer for deflecting the overlying dural sac”; “expandable and contractable internal layer”; “internal bottom layer having a heat generator therein”; “internal middle layer providing thermal insulation”; internal top layer for deflecting the overlying dural sac...” must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet”

pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

The amendment filed April 14, 2006 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: “the energy application head having a length a width and a height, said length being at least three times said width, said height being less than half said width.”

Applicant is required to cancel the new matter in the reply to this Office Action.

With regard to the art rejections, the Baker and Lax et al references read on the claims as the examiner has already set forth. Applicant has provided no convincing reason why these interpretations of the references do not read on the claim limitations to which they are applied, but has merely relied on previous arguments, already found to be unpersuasive. With regard to the teachings of Baker, applicant's attention is respectfully invited to, for example Figure 2 of Baker to illustrate the “elongated, relatively flat” construction of one of the electrodes therein, the flexibility of the electrode is discussed at column 7, lines 43-53, thus, as the electrode of Baker is elongated, relatively flat and flexible, it falls within applicant's definition of “ribbon-like” also set forth at page 17 of the originally filed disclosure. Similarly the Lax et al reference, at Figures 2, 3, 7, 9, and 10 shows a layer, which is elongated and flat, while the flexibility thereof is demonstrated in Figure 5, for example, thus this element meets the “ribbon-like” limitation in the same manner as that of Baker. With regard to the limitations of claim 8, the

antenna in Figures 7 and 10 of Lax et al and Baker, respectively would constitute a “bottom layer having a heat generator therein” to the extent such an element disclosed by applicant can. Also, with regard to the two references, in addition to the fact that materials expand and contract with heating and cooling, respectively, this limitation is also met by those embodiments employing a liquid or gel conductive medium, which will inherently be a variable distance energy application region, by virtue of the fact that it flows, and thus would read on the argued limitations of claims 9, 13-16, and 18.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 2 and 33-35 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claim 2 recites the device “having a surface that contacts a treatment area”. This phrase positively recites the body, which is non-statutory.

Claims 22 and 26-29 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The originally filed disclosure and the disclosure or amended is silent as to the various factors needed and the manipulations thereof required for “calculating an amount of energy needed to refurbish thermally said at least one intervertebral disc.” and dimensions such

that “the energy application head having a length a width and a height, said length being at least three times said width, said height being less than half said width.”

The claim language recites height, width, and length, while the disclosure at page 16 discusses only thickness; expanded thickness; and length. Since only two specific dimensional relations are disclosed in the specification, any claim to three such relations is new matter.

Claims 4 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 4 is indefinite because the exact meaning of the term “heat generation layer” is unclear.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 3, 4, 9, 10, and 12 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Lieber.

Lieber teaches a ribbon like electrode, wherein parts thereof are internal (internal energy transmission layer), and wherein the ribbon can be NICHROME TM, which will inherently heat up when electrical energy is passed through it various segments of the electrode each constituting a heating element.

Claims 1-8 and 26 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Garito et al.

See Figures 1-3 and column 2, lines 31 to 66.

Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Baker.

Baker teaches a thermal applicator, which can include an insulative (protective) layer (see Figure 11), which can be used for annuloplasty (see Figures 15 and 16), and which when so used will deflect the dural sac and nerve roots on insertion. Since the device can expand and contract with temperature, it is considered expandable and contractible as claimed. Since the energy application surface in e.g. Figure 11 is an electrically conductive fluid or gel, the surface thereof will be a variable distance from the insulative layer.

Claims 1, 2, 9-20, 23, 24, and 33-35 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Ingle et al.

See Figures 15-20 and column 5, line 6 to column 17, line 50.

Claims 1, 2, 9-16 and 18-21 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Lax et al.

Lax et al. teaches a thermal applicator which can include an insulative (protective) layer (see Figure 9), which can be used for annuloplasty (see Figures 22 and 23), and which when so used will deflect the dural sac and nerve roots on insertion. The device can also have a dome shape (see Figure 10). Since the device can expand and contract with temperature, it is considered expandable and contractible as claimed and since the expansion will be in proportion to the temperature rise, the distance will be automatically and mechanically variable in proportion to the amount of energy being delivered. Since the energy application surface in e.g.

Figure 9 is an electrically conductive fluid or gel, which is under physician control (see Figure 11) the surface thereof will be a manually variable distance from the insulative layer

Claims 3-8 and 27-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ingle et al. in combination with Yang et al. Lax et al teach a device such as claimed, as set forth above. Yang et al teach the desirability of providing coatings on electrodes. It would have been obvious to the artisan of ordinary skill to provide a coating on the device of Ingle et al, since this would provide greater durability and consistent treatment, as taught by Yang et al, and to provide the claimed dimensions, since these are not critical, are well within the scope of one having ordinary skill in the art, and provide no unexpected result, thus producing a device such as claimed.

Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lax et al. in combination with Ingle et al. Lax et al teach a device and method such as claimed, as set forth above. Ingle et al teach a surgical system wherein an inflatable element is used to protect tissue from the treatment energy. It would have been obvious to the artisan of ordinary skill to employ an inflatable device and method as taught by Ingle et al in the device and method of Lax et al, since this is equivalent to the non-inflatable tissue protective elements, as shown by Ingle et al; is not critical; and provides no unexpected result, or to treat discs, as taught by Lax et al in the method of Ingle et al, since Ingle et al teaches that the method can be used on a variety of tissues, thus producing a method such as claimed.

Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lax et al. in combination with Danon and Coleman. Lax et al teach a device and method such as claimed, as set forth above. Danon teaches a surgical system wherein a predictive element determines and

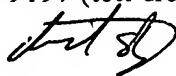
displays the determined results of the next application of treatment energy prior to administering the energy. Coleman teaches measuring the amount of tissue shrinkage based on measurements of untreated tissue and the energy applied. It would have been obvious to the artisan of ordinary skill to employ a device and method as taught by Danon in the device and method of Lax et al, since this would provide greater patient safety and to employ the data of Coleman to make the determination of Danon, since Danon gives no means by which this determination can be made, thus producing a method such as claimed.

Applicant's arguments filed April 14, 2006 have been fully considered but they are not persuasive. The arguments are not persuasive for the reasons set forth above.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to david shay whose telephone number is (571) 272-4773. The examiner can normally be reached on Tuesday through Friday from 6:30 a.m. to 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II, can be reached on Monday, Tuesday, Wednesday, Thursday, and Friday. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


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